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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,350	04/18/2006	Masayuki Yoshikawa	VX062734 PCT	7216

23400 7590 05/12/2009

POSZ LAW GROUP, PLC
12040 SOUTH LAKES DRIVE
SUITE 101
RESTON, VA 20191

EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,350	YOSHIKAWA ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 13-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skill in the art how to make and/or use the full scope of the claimed invention.

(A) The breadth of the claims.

Claims 13-24 encompass a method of preventing or treating disease caused by the formation of advanced glycation products or aldose reductase activity. On page 8 of the specification it is stated that the diseases include diabetic complications, Alzheimer's disease, amyotropical lateral sclerosis, dialysis amyloidoses, arthrorheumatism and peripheral effects of diabetes or galactosemia. However, there is no known correlation between the activity relating to the inhibition of formation of advanced glycation end product and the prevention or treatment of various disease encompassed by the present claims.

The term "preventing" encompasses administering the active compound to healthy subjects and preventing said subjects from ever getting the diseases encompassed by the present claims.

(B) The amount of direction provided by the inventor.

The aldose-reductase-inhibiting activity test set forth on pages 17-18 of the specification is clearly not commensurate with the scope of the claimed invention.

(C) The existence of working examples.

No examples relating to the prevention or treatment of any specific disease has been set forth in the specification.

(D) The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Because there is no way to predict a priori for the prevention or treatment of which specific disease the claimed methods would be useful, it would take an enormous amount of trial and error to test anthocyanins for the prevention or treatment of a large number of potential diseases.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 13-24 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent No. 1 318 201 A1.

The European Patent discloses the claimed compound anthocyanin and its use in foods and pharmaceuticals. The prevention of a disease caused by the formation of advanced glycation end products would have been inherent in the uses disclosed by the European

Applicant's arguments filed February 5, 2009 have been fully considered but they are not persuasive.

Applicant contends that the European Patent fails to disclose any pharmaceutical compositions comprising anthocyanin and fails to disclose any activities of purified anthocyanidin glucoside. This arguments have not been found persuasive. The European Patent teaches on page 2, paragraph [0006] that when 'these anthocyanins having pharmacological properties are used as pharmaceuticals and the like, highly purified ones are required". The preamble to the compound claims 1-4 has been considered but does not overcome the rejection since it does not change the basic characteristics of the claimed compound. The claimed compound is still old. New use for an old compound does not make an old compound patentable.

The method claims 13-24 read on preventing a disease i.e. said claims encompass administration of anthocyanin to a patient who does not have the disease and preventing said patient from ever getting said disease. Since the European Patent discloses the use of anthocyanins in food and pharmaceuticals (page 2), the prevention of a disease caused by the formation of advanced glycation end products would have been inherent in the uses disclosed by the European Patent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623